Great Ships Initiative

GREAT SHIPS INITIATIVE (GSI)

TECHNICAL SYSTEMS AUDIT CHECKLIST FOR SAMPLES COLLECTED DURING INTAKE

Purpose/Scope of Audit: **GSI Research, Development, Testing, and Evaluation (RDTE) Facility Technical Systems Audit**

Brief Description of Audit: Audit of sample labeling, collection, transport, and analysis at the GSI RDTE Facility during performance evaluation of the Siemens SiCURE Ballast Water Management System (Trial #4). Quality system documentation will be reviewed. A procedural audit will be conducted to verify that the technical aspects of this project are being performed according to GSI standard operating procedures.

Auditee: GSI scientists

Audit Location: RDTE Facility (Superior, WI)

Auditors: Kelsey R. Prihoda, GSI Assistant Quality Assurance Manager

Audit Dates: Friday, September 11, 2009

SAMPLE BOTTLE LABELING, SAMPLE COLLECTION, AND SAMPLE TRANSPORT TO UWS

SAMPLE TEST ID: 09-SI-4F

Relevant GSI SOPs:

- *GSI/SOP/G/RA/SC/3 – Procedure for Labeling Samples Collected at the GSI Land-Based RDTE Facility (DRAFT)*
- *GSI/SOP/LB/G/O/5 – Procedure for Injecting Organisms and Solids into the GSI Land-Based RDTE Facility*
- *GSI/SOP/LB/RA/SC/3 – Procedure for Algae/Small Protozoa Sample Collection*
- *GSI/SOP/LB/RA/SC/4 – Procedure for Microbial Sample Collection*
- *GSI/SOP/LB/RA/SC/6 – Procedure for Zooplankton Sample Collection*
- *GSI/SOP/LB/RA/SC/3 – Procedure for Collecting Physical/Chemical Data and Samples at the GSI Land-Based RDTE Facility (DRAFT)*

Filling C2/T2

- **Time Fill Started:** 9:51 am Chemistry + Water Quality Collection @ 10:01, 10:21, 10:41
- **Time Fill Completed:** 10:48 am

Sample Collection Type (Code)	Sample Port/Point	Tub Number	Sample Type (Collected By)	Labeled Correctly & In Crate?		Collected Following SOPs?		Transported Back to UWS?	
				Y	N	Y	N	Y	N
Before Fill (BF)	Pond		Phytoplankton (Euan)	✓		✓			
Before Fill (BF)	SP2	3	Harbor Phytoplankton (Don/AMI)	✓		✓			
			Harbor Zooplankton (Don/AMI)	✓		✓			
Control Tub	SP2	1	TRC and TRO (Lana)	✓		✓ (10:51)			

Initial/Date

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Sample Collection Type (Code)	Sample Port/Point	Tub Number	Sample Type (Collected By)	Labeled Correctly & In Crate?		Collected Following SOPs?		Transported Back to UWS?		
				Y	N	Y	N	Y	N	
(C)			Chem. Bucket (Don)	✓		✓				
			Phytoplankton (Euan)	✓		✓ 10:51				
			Zooplankton (Don)	✓		✓ 11:45				
Pre-Treatment Tub (PT)	SP3	4	TRC and TRO (Lana)	✓		✓ 10:54				
			Chem. Bucket (Don)	✓		✓ 10:52				
			Phytoplankton (Euan)	✓		✓ 10:52				
			Zooplankton (Don)	✓		✓ Received 11:27				
			Microbe Rep. 1 (Lana)	✓		✓ 10:53		✓		Heidi Saillard to Transport
			Microbe Rep. 2 (Lana)	✓		✓ 10:53		✓		
			Microbe Rep. 3 (Lana)	✓		✓ 10:53		✓		
Pre-Treatment In-Line (PT)	SP3		TSS, POC, DOC Rep. 1 – 10 min. (Heidi Schaeffer)	✓		✓ 10:02		✓		
			TSS, POC, DOC Rep. 2 – 30 min. (Heidi Schaeffer)	✓		✓ 10:21		✓		
			TSS, POC, DOC Rep. 3 – 50 min. (Heidi Schaeffer)	✓		✓ 10:41		✓		
Filter Backwash (BW)	Line to Backwash Storage Tank		TRC and TRO Rep. 1 – Beginning (Lana)	✓		✓ 10:06				
			TRC and TRO Rep. 2 – Middle (Lana)	✓		✓ 10:25				
			TRC and TRO Rep. 3- End (Lana)	✓		✓ 10:45				
			Disinfection Byproducts Rep. 1	✓		✓ 10:41		✓ 12:08		Tom to transport
			Disinfection Byproducts Rep. 2	✓		✓ 10:41		✓ 12:08		
Post-Treatment Tub	SP15	6	Phytoplankton	✓		✓ 10:54				
			Zooplankton	✓		✓ recieved @ 12:46				

Tub 6 is very rusty compared to Tubs 1 and 4.

Initial/Date

KMP 9-11-09

Sample Collection Type (Code)	Sample Port/Point	Tub Number	Sample Type (Collected By)	Labeled Correctly & In Crate?		Collected Following SOPs?		Transported Back to UWS?		
				Y	N	Y	N	Y	N	
(T)			Cold Water Bioassay	✓		✓ 10:57		✓		
			Chem. Bucket	✓		✓				
			Microbe Rep. 1	✓		✓ 10:56		✓		
			Microbe Rep. 2	✓		✓ 10:56		✓		
			Microbe Rep. 3	✓		✓ 10:56		✓		
			Disinfection Byproducts Rep. 1	✓		✓ 10:56		✓ 12:08 Tom to transport.		
			Disinfection Byproducts Rep. 2	✓		✓ 10:56		✓ 12:08		
			TRC and TRO	✓		✓ 10:56				
Post-Treatment In-Line (T)	SP16 Without new pitot design - i.e., pitot with holes.		TSS, POC, DOC Rep. 1 – ~10 min. (Tom)	✓		✓		✓		Heidi Saillard to transport
			TSS, POC, DOC Rep. 2 – ~30 min. (Tom)	✓		✓		✓		
			TSS, POC, DOC Rep. 3 – ~50 min. (Tom)	✓		✓ 10:42		✓		
			TSS, POC, DOC Rep. ~~3~~ 1 – ~50 min. Duplicate (Tom)	✓		✓		✓		
			TRC and TRO Rep. 1 – ~10 min. (Tom)	✓		✓				
			TRC and TRO Rep. 2 – ~30 min. (Tom)	✓		✓ 10:24				
			TRC and TRO Rep. 3 – ~50 min. (Tom)	✓		✓ 10:44				
Post-Treatment In-Line (T)	Siemens TAP (S TAP)		TRC and TRO Rep. 1 – ~10 min. ① ~~(Tom)~~ Lana	✓		✓ 10:01				
			TRC and TRO Rep. 2 – ~30 min. ① ~~(Tom)~~ Lana	✓		✓ 10:21				
			TRC and TRO DUP Rep. ~~2~~ 1 – ~30 min. ① ~~(Tom)~~ Lana	✓		✓ 10:01				
			TRC and TRO Rep. 3 – ~50 min. ① ~~(Tom)~~ Lana	✓		✓ 10:41				

① RE KMP 9-11-09

Initial/Date

KMP/9-11-09

COMMENTS OR OBSERVATIONS DURING FILL AND SAMPLE COLLECTION:

SAMPLE ANALYSIS

SAMPLE TEST ID: 09-SI-4F

QUALITY SYSTEM DOCUMENTATION

AUDIT QUESTIONS	RESPONSE			COMMENTS
	Y	N	NA	
1. Is there an approved Quality Assurance Project Plan for the overall project and has it been reviewed by all appropriate personnel?		✓		There is a DRAFT GSI QAPP that has not been reviewed by all GSI personnel yet.
2. Is a copy of the current approved QA Project Plan maintained near laboratory work station areas?			✓	
3. Is the implementation of the project in accordance with the QA Project Plan?			✓	
4. Are there deviations from the QA Project Plan? Explain.			✓	
5. Do any deviations from the QA Project Plan affect data quality?			✓	
6. Are sample handling and storage procedures in accordance with the QA Project Plan?			✓	Sample handling and storage procedures are in accordance with the GSI SOPs listed in this document.
7. Are written and approved current standard operating procedures (SOPs) used in the project? If so, list them and note whether they are maintained near laboratory work station areas?	✓			GSI SOPs are listed in this document. They are maintained in the mobile lab and are with GSI QA staff at all times.
8. Are data/observations appropriately recorded in laboratory notebooks/forms according to the QA Project Plan (i.e., entries in ink, dated, initialed, corrections done properly)? Are data contained in bound, well-labeled notebooks or three-ring binders?	✓			All data recording observed was done according to GSI SOPs. ZP analysis sheets are kept in 3-ring binders
9. Do supervisory and/or QA personnel inspect laboratory notebooks/forms on a regular basis and initial notebook after review?		✓		GSI notebooks have not been inspected thus far, but will be following the end of Siemens SCARE testing
10. Are paper records written in indelible ink?	✓			All observed recording was in indelible ink.

Additional Questions or Comments:

Cont'd from #8: until after they are brought back to campus (UCD).

Initial/Date

KLP / 9-11-09

CHEMISTRY

Relevant GSI SOPs:

- *GSI/SOP/BS/RA/C/2 – Procedure for Determining Total Residual Oxidants (TRO) in Water*
- *GSI/SOP/BS/RA/C/3 – Procedures for Measuring Organic Carbon in Aqueous Samples*
- *GSI/SOP/BS/RA/C/6 – Procedure for Analyzing Total Residual Chlorine (TRC) Concentrations in Water*
- *GSI/SOP/BS/RA/C/8 – Procedure for Analyzing Total Suspended Solids (TSS)*

AUDIT QUESTIONS	RESPONSE Y	N	NA	COMMENTS
1. Describe the analytical instrumentation. List the brand and model number for each instrument.	✓	✓		Orion 290 #2 – TRC Spec 20 4157 – TRO
2. Are calibration and maintenance logs kept for the instrumentation (e.g., balances and other equipment)?	✓	✓		maintenance logs are not kept The standard curve calibration is documented on pre-printed data sheets.
3. Review the maintenance and operational records for the equipment. Based on your findings, do all instruments/equipment appear to be in good operating condition?	✓			Standard curve and QC sample have results that are expected and have been repeatable.
4. Are the manufacturer's operating manuals readily available to the instrumentation operators?		✓		manuals at UWS campus.
5. Describe the routine calibration procedure.	✓			calibration using 5-pt std. curve for TRO and TRC is described in above SOPs
6. Does the calibration documentation show that the calibration procedures are being followed?	✓			Pre-printed data sheets can be used to reconstruct std. curve preparation.
7. Do the calibration standards have the appropriate levels (i.e., bracket the samples to be measured)?	✓			See #12 below.
8. What is the instrumentation calibration error according to the calibration documentation?			✓	did not observe std. curve R^2 value.
9. Are duplicate samples collected and analyses conducted on at least 10% of the physical/chemical samples?	✓			From treatment side (post-trt): WQ Rep. 1 DUP and CH Rep. 1 DUP. 4/6 1/9
10. Are reagent blank samples analyzed with each set of samples?	✓			
11. Are a minimum of three and preferably more standards required for standard curves?	✓			5-point standard curve for TRC and TRO Plus QC std. analyzed.
12. When applicable, do routine procedures that require standard curves bracket concentrations?	✓			Siemens dosing at ~6mg/L Chlorine. TRC std. curve= ~~0.05~~, 0.1, 0.5, 1, 5, and 10.
13. When applicable, have analytical method detection limits been established and clearly documented?	✓			

Additional Questions or Comments: New pilot design at SP16 was supposed to be put in place prior to 09SI 4F, however, it didn't get installed. Therefore, it is expected that CH samples from SP16 will again be inconsistent (as seen in 09SI 3F).

Initial/Date

KMR 9-11-09

MICROBIOLOGY Reviewed datasheets 21 October 2009. UMR. Data entry proofed by TJJ 29 Sept. 09.

Relevant GSI SOPs:

- *GSI/SOP/BS/RA/MA/1 – Procedure for Quantifying Heterotrophic Plate Counts (HPCs) using IDEXX's SimPlate® for HPC Method*
- *GSI/SOP/BS/RA/MA/3 - Procedure for the Detection and Enumeration of Enterococcus using Enterolert™*
- *GSI/SOP/BS/RA/MA/4 – Procedure for the Detection and Enumeration of Total Coliforms and E. coli using IDEXX's Colilert®*

AUDIT QUESTIONS	RESPONSE Y	N	NA	COMMENTS
1. Are duplicate sample analyses conducted on at least 10% of the microbiology samples?	✓			QA count done on E.coli, Enterococcus by MJS. No QA count for HPC or VC.
2. Are at least 10% of the samples counted by a second qualified individual (i.e., QA count)?	✓			1 Duplicate for EC, TC, ENT, HPC, + VC-RNA+DNA.
3. Are ~~reagent~~ control blank samples analyzed with each set of samples? (RB) UMR 10-21-09	✓			Blanks for: E. coli, total coliforms, Enterococcus, HPC, and VC-RNA+DNA.
4. When applicable, have analytical method detection limits been established and clearly documented?	✓			

Additional Questions or Comments: Samples collected by 10:53 am, recieved in lab at 11:30 am, and neutralized by 12:25 pm. All samples in incubator by 2:08 pm. All pre-treatment TCBS plates for V. cholerae were TNTC, ∴ samples were re-filtered on 9-12-09 at 6 pm - this is ~~6.5~~ 30.5 hours more than directed in SOPs after receipt, 24.5 hours more than.

PHYTOPLANKTON

Relevant GSI SOPs: Reviewed datasheets 16 October 2009. UMR.

- *GSI/SOP/LB/RA/SA/1 – Procedure for Algae/Small Protozoan Sample Analysis*

AUDIT QUESTIONS	RESPONSE Y	N	NA	COMMENTS
1. Were all data, observations, and comments appropriately recorded on the "Ballast Water Plankton Count Sheet"?	✓			Will need to see copy or scanned document- was not present during analysis.
2. Was sample assessment conducted within ~1-1.5 hours after sample collection?		✓		Started @ 10:55. Done @ ~12:45. Samples were
3. Were at least 10% of the samples counted by a second analyst (i.e., QA count)?	✓			very concentrated and were difficult to count. Lead did 2nd count.

Initial/Date

UMR / 10-21-09

Additional Questions or Comments: ~~*Why are there so many more chains in pre-trt than control?~~ (initials) 10-16-09 ~~Control sample time rec'd must be incorrect. Sample collected at 10:15 : could not have been recieved at 10:05.~~   No error corrections.   Datasheets were difficult to read (scanned PDF copies), writing may have been done in pencil - was very faint. Diatom chains had so many cells that there was not adequate space to record all of the data - making it very difficult to add the total number of cells.   Pre-TRT: ~~1972~~ 1793 cell/mL live in Tub 4   Post-TRT: ~1 cells/mL live in Tub 6

ZOOPLANKTON

Relevant GSI SOPs:

- *GSI/SOP/BS/RA/C/2 – Procedure for Zooplankton Sample Analysis (DRAFT)*

AUDIT QUESTIONS	RESPONSE			COMMENTS
	Y	N	NA	
1. Were all data, observations, and comments appropriately recorded on the "Zooplankton Identification Worksheet"? and in ZP Analysis Log Book)	✓			
2. Was sample assessment conducted within ~2 hours after sample collection?		✓		4: started @ 11:27. Done @ 1:35. 6: ~1:15 started. rotifers/low @ 3:04. Crust @ 3:27
3. Were at least 10% of the samples counted by a second analyst (i.e., QA count)?	✓			Second count done by HLS on Pre-Trt Tub 4 sample.
Additional Questions or Comments: 4.7×10^5 zooplankton in harbor. 10-1-09: Pre-Treatment Fill Tub 4 rotifer subsamples 1 and 2 had 274 and 352 orgs/slide. This exceeds the 150-200 orgs/slide specified in the SOP.				

Additional Questions and Comments on Technical Systems Audit:

- New injection pump was installed prior to 09 SI 4F, therefore, TSS should be approximately 60 mg/L in today's 'pre- and post-treatment' samples.
- Siemen's chemist will analyze TRC on Tub 6 sample after our analysis for comparison purposes.
- Don added YSI probes for in-tank water chemistry monitoring to C2 and T2.

Initial/Date

KMP/9-11-09